



## Indian Society for Clinical Research Announces a One-Day workshop

### **EVOLVING REGULATORY LANDSCAPE: OPPORTUNITIES & CHALLENGES!!**

#### **Schedule:**

<b>Date</b>	<b>Time</b>	<b>Venue</b>
30-Oct-15	8:30 am – 6:00 pm	<b>Mumbai – Hotel Orchid</b> , 70C, Nehru Road, Near Sahara Hotel, Vile Parle East, Mumbai
27-Nov-15	8:30 am – 6:00 pm	<b>Bangalore –Goldfinch Hotel</b> , # 32/3, Crescent Road, Off High Grounds, Race Course Road, Bengaluru – 560 001
04-Dec-15	8:30 am – 6:00 pm	<b>Delhi – India Habitat Centre</b> , Lodhi Road, Near Airforce Bal Bharati School, New Delhi, Delhi 110003, India

**INTRODUCTION:** This one day workshop designed to present & clarify the evolving regulatory landscape especially over the last one year. Topics mentioned in this draft flyer will make this interface useful and interesting for professionals with Clinical Research.

**SCOPE:** To provide an overview of the recent developments governing the process of filing, review and approval of Clinical Trial applications including relevant recent updates.

**TARGET AUDIENCE:** Regulatory & Clinical Research Associates of Sponsors & CROs

## Agenda – 27-Nov-15, Bangalore Workshop

Time	Topic	Speaker
8:30 am to 9:00 am	Registration & Tea	
9:00 am to 9:15 am	Welcome	South Zone organizing team
9:15 am to 10:00 am	How to build compile high quality regulatory submissions -best practices	Mr. Somaiah Muckatira (Stempeutics)
10:00 am to 11:15 am	CTAs: Recent changes - application process - review and approval process	Mr. Jayasheel Gangaiah (Alcon)
11:15 am to 11:45 am	<b>TEA BREAK</b>	
11:45 am to 12:15 pm	How to optimize clinical operations and regulatory affairs collaboration	Mr. Prasad Shetty (Quintiles)
12:15 to 12:45 pm	Accreditation of Investigators, Sites and ECs: updates	Ms. Mala Shrivastava (Nextvel Consulting)
12:45 to 1:15 pm	Compensation and safety -Journey from 2013 to 2015	Mr. Bhavesh Kotak (Astra Zeneca) / Dr. Gaurav Mathur (Quintiles)
1:15 to 2:00 pm	<b>LUNCH BREAK</b>	
2:00 to 2:45 pm	Career Development – Learning from seniors	Dr. Jahanara Rahuldev (Parexel), Dr. Premnath Shenoy  Facilitator: Gaurav Mathur
2:45 to 3:15 pm	D&C amendment bill and rules - updates	Dr. Premnath Shenoy / Mr. Jayasheel Gangaiah (Alcon)
3.15 – 3:45 pm	<b>TEA BREAK</b>	
3:45 to 5:45 pm	Panel Discussion: SEC functioning - Investigator - SEC expert - Regulator Industry representative	Investigators – Dr. P. P. Bapsy (Apollo Hospitals), Dr. Prem Pais (St. John's)  SEC Expert – Dr. Raju Titus Chacko (CMC, Vellore)  Regulators- Mr. Somnath Basu or Dr. B R Jagashetty  Industry- Dr. Vikas Sharma (Quintiles), Dr. Ramesh Jagannathan (Novo Nordisk), Dr. Jahanara Rahuldev (Parexel)  (Facilitator- Gaurav Mathur)
5.45 – 6.00 pm	Wrap Up and Conclusions	South Zone organizing team

## **Registration details:**

**No. of Participants: 50**

**Delegate Fee:**

For ISCR Members – Rs 2500/-

For Non-Members – Rs 3000/-

**Mode of Payment:** 1) Online 2) Cheque/DD

**Online registration (compulsory):** - [http://www.iscr.org/events\\_MemberRegistration.aspx](http://www.iscr.org/events_MemberRegistration.aspx)

**Online Payment link:** <http://www.iscr.org/Events.aspx>

**Cheque/DD:** Payable at Mumbai should be made in favor of “**Indian Society for Clinical Research**”

Mailed to us at: ISCR Secretariat, C/o Pfizer Centre, Patel Estate, S.V. Road, Jogeshwari (W),  
Mumbai – 400 102

**For any query please feel free to write to [info@iscr.org](mailto:info@iscr.org) org call on **+91-22- 6693 2028/2440****